

REMARKS

The Office Action of August 16, 2005, has been carefully considered.

The Examiner has issued a requirement for information in accordance with 37 CFR 1.105, requesting a submission from the Applicant regarding anaerobic threshold testing, and in particular information distinguishing the testing methods of the invention from the standard protocols.

In response, Applicant submits the following documents:

International Journal of Sports Medicine, No. 3, Volume 2, August 1981, pages 160-165, containing information on the anaerobic threshold;

International Journal of Sports Medicine, No. 2, Volume 3, May 1982, pages 105-110, including a comparison between the individual anaerobic threshold of the inventor and classic methods of determining a fixed anaerobic threshold;

European Journal of Applied Physiology and Occupational Physiology 67:125-131 (1993), providing an overview of how the anaerobic threshold is determined in accordance with the Stegmann method and with classical methods in the US;

ISPCS Individual Standard of Physical Working Capacity, disclosing how individual anaerobic threshold and lactate accumulation rate  $\Delta A$  are determined and conclusions which can be drawn from these. Determination of lactate accumulation rate is also discussed in the Stegmann US Patent No. 6,809,676; and

Journal of Physiology (2002), pages 963-975, containing an explanation that when lactate concentration is increased, glucose oxidation is decreased.

It is noted that the ISPCS and Journal of Physiology references are not prior art to the present invention.

Objection has been raised to Claim 24, and this claim has

now been canceled.

It is noted that the claims of record have now been canceled and rewritten as new Claims 26 through 29. Claim 26 incorporates the recitations of Claims 20, 21 and 24.

The claims continue to be rejected under 35 USC 101 on the basis that the invention is directed to non-statutory subject matter, in that the claimed invention fails to produce a "useful, tangible and concrete result." The Office action continues to cite *In re Warmerdam* and *In re Schrader* even though these cases cite the Freeman-Walter-Abele test, which was effectively overruled in the *State Street Bank* case, as noted in the previous response. *State Street Bank* held that a useful, concrete and tangible result could be no more than numbers such as price, profit, percentage, cost or loss. Further, *State Street* held that even though a claimed invention involves in-putting numbers, calculating numbers, out-putting numbers and storing numbers, this would not render the invention non-statutory subject matter unless the operation did not produce a useful, concrete and tangible result (47 USPQ2<sup>nd</sup> at 1602).

The Office alleges that the present claims do not require the performance of physical steps, and in this regard, the Office action states that "[t]he first determination step does not require a physical measurement. In fact, a well known means of measurement of anaerobic threshold occurs when the person mentally calculates anaerobic threshold as 80-90% of a person [sic] maximum heart rate or just the point at which a person can't talk without gasping for breath." Applicant argues that to the contrary, conducting a test on a person to determine the person's maximum heart rate is a physical measurement, whether that heart rate is written down or inputted to a computer, because it is a *physical measurement*

made upon a person under a specific set of circumstances. No reason is seen why such a step is not a physical step. Moreover, Claim 26 now recites that one must measure the lactate accumulation rate  $\Delta A$  of the person at and above the individual anaerobic threshold. Measuring the lactate accumulation rate of a person is certainly a physical step, as opposed to a mental step, because a physical measurement is involved, and in particular requires the measurement of time dependent lactate concentration change beyond the individual anaerobic threshold. Certain method steps must also be carried out, including plotting a measurement curve and determining two gradients in the curve, and subtracting the second gradient from the first gradient. While these steps may be mental steps, they cannot be carried out until a physical step is carried out first.

In addition, there is a concrete, useful and tangible result of the invention. As can be seen from the table on page 7 of the application, the data obtained is used to regulate carbohydrate, fat and protein consumption. The Office action alleges that the regulation step can be performed by doing nothing, assuming the person is already performing the prescribed nutrition regiment. However, the regulation step is the output of the process, which is an *affirmative recitation* of the nutrition that the person should be receiving based upon measure data.

Thus, the claimed invention is fully in compliance with the requirements of the *State Street Bank* case, and withdrawal of this rejection is requested.

Claims 20 through 25 have also been rejected under 35 USC 112, first paragraph, on the basis that the claimed invention is not supported either by a specific and substantial asserted utility or a well established utility. This rejection is not

understood; the utility of the invention is quite clear, determining preferred nutrition from measurements made on an individual, and withdrawal of this rejection is requested.

Claims 20, 21 and 25 have been rejected under 35 USC 012(b) as anticipated by Chance. In view of the submission of new claims including the recitations of Claims 20, 21 and 24, this rejection will be considered together with the rejection of Claims 22 and 24 under 35 USC 103(a) over Chance.

The Chance reference discloses evaluating muscle efficiency of a subject with an apparatus comprising a nuclear magnetic resonance analysis device. As disclosed in columns 8 and 9, the various phosphorus components in the tissue are evaluated, including the concentrations of inorganic phosphate (PI) and phosphocreatine (PCR). The ratio PI/PCR is a measurement of the biochemical cost of the work performed by a muscle, and this ratio is measured with different stresses, and during the stress measurement a steady state is necessary (column 9, line 10).

In contrast, the invention provides measurements with changing stresses, since both the individual anaerobic threshold and the lactate accumulation rate must be determined.

Moreover, Chance utilizes measurements where the person is subjected to work which does not exceed the anaerobic threshold. See column 10, lines 31-47. The anaerobic threshold is then determined by extrapolation, and there is no suggestion of regulating nutrition from the extrapolated anaerobic threshold value. There is further no suggestion of measuring the lactate accumulation rate.

The Office action alleges that Chance teaches regulating at least one of fat, protein and carbohydrate consumption at column 11, lines 43-45, but in fact, the disclosure at column

11, lines 43-45 only indicates that the invention can also monitor different training and nutritional programs while detecting over-training. There is no disclosure or suggestion of regulating one of fat, carbohydrate and protein based on the measurements made. Chance appears to do the opposite, determining the effectiveness of an already in place nutritional program.

Withdrawal of these rejections is accordingly requested.

Finally, Claim 23 has been rejected under 35 USC 103(a) over Chance in view of Kornstad et al. Chance has been discussed in detail above, and Kornstad et al discloses the use of a protein-rich low calorie diet powder in connection with an exercise physical performance test. However, Chance does not disclose regulating nutrition based upon stress, individual anaerobic threshold and lactate accumulation rate, and the combination of Chance and Kornstad et al does not suggest the invention as recited in Claim 23. Withdrawal of this rejection is requested.

In view of the foregoing amendments and remarks, Applicant submits that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,



Ira J. Schultz

Registration No. 28666